

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED
CENTRAL FAX CENTER

In re Application of:

WALLACE K. DYER

Serial No. 09/943,138

Filed: August 30, 2001

For: METHODS AND COMPOSITIONS
FOR TISSUE AUGMENTATION

Art Unit: 1639

Examiner: Jon D. Epperson

JAN 31 2006

**DECLARATION OF WALLACE K. DYER, M.D. PURSUANT
TO 37 C.F.R. § 1.131**

I, Wallace K. Dyer, declare the following:

1. I am over the age of 21 and am competent to make this declaration based on personal knowledge.
2. I am a board certified facial plastic surgeon and a board certified otolaryngologist, head and neck surgeon and have been in practice for the past 20 years. I am a Fellow of the American Academy of Facial Plastic and Reconstructive Surgery, the American Academy of Otolaryngology, Head and Neck Surgery, and the American College of Surgeons (F.A.C.S.).
3. I am the sole inventor of the subject matter disclosed and claimed in United States Patent Application Serial No. 09/943,138 filed August 30, 2001, which claims priority to: United States Provisional Patent Applications 60/229,085, filed August 30, 2000; 60/229,989, filed September 5, 2000; and, 60/241,636, filed October 19, 2000.
4. This document is submitted as evidence that the subject matter recited in the pending claims, including claims 1, 4, 7-11, 13, 15, and 17-29, of United States Patent Application Serial No. 09/943,138 was conceived prior to May 19, 2000 and diligently reduced to practice thereafter.
5. I conceived of the subject matter recited in the pending claims of United States Patent Application Serial No. 09/943,138 in the United States at least as early as

Exhibit A

Application No. 09/943,138
Declaration of Wallace K. Dyer, M.D. Pursuant to 37 C.F.R. § 1.131
Attorney Docket: 37370-323869 (0200)
Page 2 of 3

December, 1999. On December 3 and 4, 1999, I attended a confidential meeting with Dr. Stephen Perkins in Indianapolis, Indiana, in which I disclosed my invention comprising methods and compositions for soft tissue augmentation. During the meeting, I described to Dr. Perkins materials suitable for use in compositions of my invention. These materials included high density polyethylene microparticles. I additionally described to Dr. Perkins methods for injecting a composition comprising high density polyethylene microparticles in a physiological carrier, such as polyvinylpyrrolidone, into soft tissue for correction or repair of defects in the tissue. I also disclosed to Dr. Perkins my concept of additional materials that could be used in the compositions and methods of the present invention including Bioglass, vicryl, Prolene, nylon and PTFE. Dr. Perkins has provided a Declaration attesting to my disclosure of my concept to him which is filed concurrently herewith.

6. I worked on the subject matter of the above-identified United States Patent Application in the United States. Following conception of the invention, I diligently reduced the invention to practice both by filing a patent application and by actually reducing the invention to practice.

7. The present non-provisional patent application (Serial No. 09/943,138) was filed August 30, 2001. It discloses solid polymer particles as biocompatible (micronized) polyethylene particles made from MEDPOR in paragraphs 0030, 0043 and 0058 and in the Abstract. The polyethylene in MEDPOR is high density polyethylene.

8. I approached Porex Corporation at least as early as September of 2001. During October of 2001 I discussed with Porex Corporation my concept of the invention, including the use of high density polyethylene particles suspended in a physiological carrier, such as polyvinylpyrrolidone, for use in soft tissue augmentation. Subsequently, numerous conversations occurred to plan the preparation and testing of the composition. The composition of high density polyethylene particles suspended in the physiological carrier, polyvinylpyrrolidone, was prepared and characterized during 2002 and tested clinically in animal studies conducted at Mercer University in March of 2003.

Application No. 09/943,138
Declaration of Wallace K. Dyer, M.D. Pursuant to 37 C.F.R. § 1.131
Attorney Docket: 37370-323869 (0200)
Page 3 of 3

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: January 27, 2006



Wallace K. Dyer, M.D.